

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 21-1015 (GBW)
)	
SAREPTA THERAPEUTICS, INC.)	DEMAND FOR JURY TRIAL
)	
Defendant.)	
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)	
SAREPTA THERAPEUTICS, INC. and THE)	
UNIVERSITY OF WESTERN AUSTRALIA,)	
)	
Defendant/Counter-Plaintiffs,)	
)	
v.)	
)	
NIPPON SHINYAKU CO., LTD.)	
and NS PHARMA, INC.,)	
)	
Plaintiff/Counter-Defendants.)	

**NIPPON SHINYAKU CO., LTD. AND NS PHARMA, INC.'S OPPOSITION TO
SAREPTA THERAPEUTICS, INC. AND THE UNIVERSITY OF WESTERN
AUSTRALIA'S MOTION TO STAY ANTITRUST COUNTERCLAIM DEADLINES
PENDING RESOLUTION OF MOTION TO BIFURCATE AND STAY**

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Dated: September 28, 2023

Plaintiffs Nippon Shinyaku Co., Ltd. and NS Pharma, Inc. (collectively, “NS”) oppose the motion to stay all antitrust related deadlines pending resolution of the motion to bifurcate and stay antitrust counterclaim (D.I. 353) (“Motion” or “Mot.”) filed by Sarepta Therapeutics, Inc. and the University of Western Australia (collectively, “Sarepta”). The Motion repeats Sarepta’s rhetoric regarding why bifurcation and a stay is purportedly appropriate, which for the reasons in NS’s Opposition to the underlying motion (D.I. 356) it is not, and paints an inaccurate and misleading picture regarding discovery in this matter. Sarepta claims that “discovery has not even begun on the antitrust issues” (Mot. at 1). Sarepta is incorrect. The parties have taken extensive discovery on issues including the product market, competitors, pricing of the accused products, and the prosecution history of the patents at issue in the antitrust counterclaims. This discovery was all NS’s expert needed to proffer opinions regarding antitrust damages in his expert report served weeks ago on September 8, and it is all that Sarepta’s antitrust damages expert needs to timely serve a rebuttal expert report as-scheduled on October 5. Thus, there is no need for a stay, which will only serve to derail the current schedule and delay resolution of NS’s antitrust counterclaim.

I. NATURE AND STAGE OF THE PROCEEDINGS.

On August 3, 2023, this Court granted NS’s motion to amend to add counterclaims for inequitable conduct and *Walker Process* fraud and also granted Sarepta’s motion to amend to add an inequitable conduct counterclaim. *See* D.I. 317. In granting NS’s motion to amend, the Court found there was no prejudice to Sarepta because Sarepta already had in its possession the evidence necessary to the antitrust counterclaim. *See* D.I. 356-1 (excerpts from Aug. 3, 2023 Hr’g Tr.) at 36:20-23 (“NS’s . . . Walker Process fraud claims *turn on evidence within the patentee’s control, i.e., Sarepta*[.]”) (emphasis added).

NS timely served its opening expert report regarding its antitrust counterclaim on September 8, 2023. *See* D.I. 350. Sarepta's rebuttal expert reports are due to be served on October 5, 2023, with expert discovery closing in November 2023. *See* D.I. 341.

II. LEGAL STANDARD

A stay is an "extraordinary measure." *United States v. Breyer*, 41 F.3d 884, 893 (3d Cir. 1994). Courts have recognized that "the right to proceed in court should not be denied except under the most extreme circumstances." *Commodity Futures Trading Com. v. Chilcott Portfolio Mgmt., Inc.*, 713 F.2d 1477, 1484 (10th Cir. 1983). While a district court has discretion to stay, "in exercising this discretion, the Court must weigh the competing interests of the parties and attempt to maintain an even balance." *Dentsply Inc. v. Kerr Mfg. Co.*, 734 F. Supp. 656, 658 (D. Del. 1990). Where a requested stay would prejudice the non-movant, the moving party must make "a showing of a clear case of hardship or inequity before the Court can enter a stay order." *Id.*

Courts in this District have typically considered three factors when deciding a motion to stay: (1) whether granting the stay will simplify the issues for trial; (2) the status of the litigation, particularly whether discovery is complete and a trial date has been set; and (3) whether a stay would cause the non-movant to suffer undue prejudice from any delay, or allow the movant to gain a clear tactical advantage. *See, e.g., FMC Corp. v. Summit Agro USA, LLC*, No. 14-51-LPS, 2014 WL 3703629, at *2 (D. Del. July 21, 2014).

III. ARGUMENT

Sarepta's motion invites the Court to prematurely decide to stay the upcoming October 5, 2023 deadline for Sarepta's responsive expert report regarding NS's antitrust counterclaim and disrupt the entire schedule, including trial. There is no basis for doing so here.

First, granting a stay will not simplify any issues for trial. Indeed, “a single trial will generally lessen the delay, expense and inconvenience to the parties and the courts.” *Graudins v. Retro Fitness, LLC*, 921 F. Supp.2d 456, 468 (E.D. Pa. 2013). Here, NS’s counterclaim (for which fact discovery is complete and expert discovery is underway) can efficiently be tried alongside the related patent claims given these claims are closely related. Delaware juries routinely hear such claims together at a single trial, and, there is no reason a jury cannot do so here. *See, e.g.*, D.I. 356-2 (*EIS, Inc. v. WOW Tech. Int’l* Pretrial Conference Tr., Sept. 5, 2023) at 18:11-22 (discussing during pretrial conference for recently completed trial that jury would get the “patent claims, the Walker Process claims, and the inequitable conduct claims in an [advisory] capacity” and that the court would issue a bench opinion to resolve the inequitable conduct claim). Far from simplifying issues for trial, a stay of antitrust discovery will simply mean that the parties will soon need to reopen discovery into substantially the same issues given that the invalidity and unenforceability of the asserted Sarepta patents also form part of the basis of NS’s antitrust claim and that NS’s antitrust claim and inequitable conduct claim are both rooted in the same fraudulent misrepresentations that Sarepta made in obtaining its patents. A trial date has been set for years and is now just month away. There is no reason to disrupt the trial date on all claims just months before the scheduled trial.

Second, the status of discovery weighs strongly against a stay at this late stage. Fact discovery is closed. Despite filing two briefs requesting a stay, Sarepta has neither identified a single piece of fact discovery it needs to adequately prepare its rebuttal antitrust expert report nor served (or sought leave to serve) a single discovery request regarding the antitrust counterclaim in the nearly two months since the Court granted NS leave to add the counterclaim to the case. Indeed, Sarepta’s core argument as to why the 125 hours of depositions, exchange of over 379,000

pages of documents, and responses to hundreds of discovery requests pertaining to, *inter alia*, the market, competitors, and related damages issues is insufficient is that NS's antitrust expert only cited 70 documents of the more than 19,000 produced in the litigation. Mot. at 3. That NS's antitrust expert cited only relevant documents says nothing regarding the scope of fact discovery in this case. Sarepta's antitrust expert is free to cite any of the 19,000 documents (or other relevant material) in the rebuttal expert report due to be served on October 5. Sarepta has failed to identify anything specific its expert supposedly needs additional fact discovery regarding in order to properly formulate rebuttal opinions.

As this Court has already recognized, the necessary facts underlying the antitrust counterclaim are uniquely within Sarepta's control. *See* Ex. A, Aug. 3, 2023 Hr'g Tr., at 36:20-23. And, discovery regarding the market for the parties' products and competitors therein (the same market relevant with respect to the antitrust counterclaim), the prosecution history of the Sarepta asserted patents (the same patents that NS asserts Sarepta procedure through *Walker Process* fraud in the antitrust counterclaim), and pricing of the parties products embodying the inventions claimed in the asserted patents (the same pricing necessary to assessing antitrust damages) has already been completed in this case. Using this extensive existing discovery, NS prepared and served its opening report on antitrust damages in accordance with the Scheduling Order, and there is no reason Sarepta now cannot respond to that expert report with an expert report of its own in accordance with the deadline in the Scheduling Order. There is no reason to stay discovery now when fact discovery is completed and Sarepta is just a week away from serving its rebuttal antitrust expert report.

Third, a stay would provide Sarepta a clear tactical advantage at the expense (and prejudice of) NS. If discovery were to be stayed on the antitrust claims now after Sarepta already has NS's

antitrust damages expert report and is just a week away from serving its rebuttal antitrust expert report, Sarepta will gain additional time—be that weeks or months—to prepare its responsive expert report, which contravenes the timing and sequencing set forth in the Court’s Scheduling Order. Moreover, if Sarepta is entitled to re-open discovery into the antitrust counterclaims at a later, unknown date, there is significant risk of prejudice to NS who will face inevitable memory loss and/or witness availability issues due to the passage of time. *See Hartford Underwriters Ins. Co. v. Spizzirri*, Civ. A. No. 1:09-CV-1277-BBM, 2009 WL 10669603, at *5 (N.D. Ga. Dec. 11, 2009) (stay presented “risks of faded witness memory”); *cf. Barnard v. Lackawanna Cnty.*, Civ. A. No. 3:15-2220, 2016 WL 362424, at *3 (M.D. Pa. Jan. 29, 2016) (non-moving party “may suffer injury” because the requested stay may last “for over half of a year” and it “must wait in limbo”).

Sarepta’s claim that it will need to expend resources to prepare the rebuttal expert report (Mot. at 3) is far from prejudicial. Sarepta needs to serve a rebuttal expert report per the Court’s Scheduling Order in a week, there is nothing prejudicial about proceeding in the normal course under the Court’s Scheduling Order. To the contrary, what would be prejudicial is to stop discovery mid-stream and delay NS from vindicating its rights through the antitrust counterclaim while allowing Sarepta to continue to take advantage of its improper market conduct. *Cf. Willemijn Houdstermaatschaap BV v. Apollo Computer Inc.*, 707 F. Supp. 1429, 1435 (D. Del. 1989) (“[P]rejudice . . . may simply amount to unfair delay of the final disposition of the matter.”).¹

¹ Sarepta’s citation to this Court’s decision to grant a stay of a patent infringement litigation in *Bataan Licensing LLC v. DentalEZ, Inc.*, C.A. No. 22-CV-238, 2023 WL 143991 (D. Del. Jan. 10, 2023) is inapposite. That case did not involve antitrust claims and the significant consequences resulting from a competitor to unfairly continue to benefit from a market advantage it would otherwise not have had but for its anticompetitive conduct. *Cf. Procter & Gamble Co. v. CAO Grp., Inc.*, No. 1:13-CV-337, 2013 WL 6061103, at *3 (S.D. Ohio Nov. 18, 2013) (recognizing

IV. CONCLUSION

The Court should reject Sarepta's request to stay discovery regarding NS's antitrust counterclaim pending resolution of Sarepta's motion to stay and bifurcate the antitrust counterclaim. Discovery on NS's counterclaim should proceed to completion now so that the counterclaim is trial ready on schedule. A stay would only give Sarepta an unfair advantage by allowing it to delay serving its rebuttal antitrust expert report, which is due in just a week.

Dated: September 28, 2023

Respectfully submitted,

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significant prejudice that could result from bifurcating and staying antitrust claim due to impossible to quantify lost market opportunities).

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